MAY 2 0 2014

1. 510(k) Summary

Device Trade Name: Acumed Suture Anchor System

Date: April 9, 2014

Sponsor:
Acumed, LLC
5885 NW Cornelius Pass Road
Hillsboro, OR 97124
Phone: (503) 627-9957
Fax: (503) 520-9618

Contact Person: Lino Tsai, Regulatory Specialist

Manufacturer:
Acumed, LLC
5885 NW Cornelius Pass Road
Hillsboro, OR 97124
Phone: (503) 207 1370
Fax: (503) 520-9618

Common Name: Screw, Fixation, Bone

Device Classification: Class II

Classification Name: Screw, Fixation, Bone

Regulation: 21 CFR 888.3040, Smooth or threaded metallic bone fixation fastener

Device Regulation Panel: Orthopedic

Device Product Code: MBI

Device Description:
The Acumed Suture Anchor System is a system for anchoring soft tissue (or soft tissue grafts), using #2 high-strength suture, back to the bone for reattachment. It is available in diameters of 4.5 mm & 5.5 mm in order to accommodate differing anatomic requirements.
The anchor is a screw designed to provide fixation to bone that comes with two, #2 high-strength suture (pre-attached) in order to secure soft tissue (or soft tissue grafts) to the anchor.
The system includes Class 1 instruments.

Intended Use:
The Acumed Suture Anchor System is designed to be used for soft tissue fixation in the foot, ankle, knee, hand, wrist, elbow, and shoulder.

Indications for Use:

The Acumed Suture Anchor System is intended to be used for suture (soft tissue) fixation to bone in the foot, ankle, knee, hand, wrist, elbow, and shoulder.

Shoulder: Rotator Cuff Repair, Bankhart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular shift or Capsulolabral Reconstruction.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair and Bunionectomy.

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair and Illiotibial Band Tenodesis.

Hand/Wrist: Scapholunate Ligament Reconstruction and Ulnar or Radial Collateral Ligament Reconstruction.

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair.

Materials:

The Acumed Suture Anchor System components are manufactured from PEEK Optima as described in ASTM F2026 and UHMWPE (High-strength suture).

Predicate Device:

A modification comparison of the proposed Suture Anchors and the predicate Suture Anchors (K133469) is provided in below Table:

K133469 Parts	Core Diameter	Outside Diameter	Description
55-0015	3.25 mm	5.5 mm	3.5 mm Suture Anchor
55-0016	4.25 mm	6.5 mm	4.5 mm Suture Anchor
Modified Parts			
55-0015	3.25 mm	4.5 mm	4.5 mm Suture Anchor
55-0016	4.25 mm	5.5 mm	5.5 mm Suture Anchor

The subject 4.5 mm and 5.5 mm Suture Anchors are substantially equivalent to predicate anchors (K133469) with respect to indications, design, function, and materials.

Preclinical Testing:
The modified Suture Anchor was subjected to static and dynamic tension along the axis of the screw as well as static and dynamic tension normal to the axis of the screw. The results demonstrate that the subject components are substantially equivalent to the predicate

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 20, 2014

Acumed, LLC
Ms. Lino Tsai
Regulatory Specialist
5885 NW Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K140925
Trade/Device Name: Acumed Suture Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: April 22, 2014
Received: April 23, 2014

Dear Ms. Tsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K140925

Device Name: Acumed Suture Anchor System

The Acumed Soft Tissue Anchor System is intended to be used for suture (soft tissue) fixation to bone in the foot, ankle, knee, hand, wrist, elbow, and shoulder.

Shoulder: Rotator Cuff Repair, Bankhart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular shift or Capsulolabral Reconstruction.

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Hand/Wrist: Scapholunate Ligament Reconstruction and Ulnar or Radial Collateral Ligament Reconstruction.

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis repair.

Prescription Use √ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices